AMS-011A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants	:	Gerald NMI Dorros *et al.*
Serial No.	:	09/972,225 Confirmation No. 4566
Filed	:	October 4, 2001
For	:	APPARATUS AND METHODS FOR TREATING A STROKE AND CONTROLLING CEREBRAL FLOW CHARACTERISTICS
Group Art Unit	:	3763
Examiner	:	Cris L. Rodriguez

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Introduction

This brief is filed pursuant to 37 C.F.R. § 1.192 to appeal a Final Rejection dated September 16, 2002, of claims 1-5, 7-9 and 26-29 of the above-identified application. A request for an oral hearing on this matter is filed herewith.

(1) Real Party In Interest

The real party in interest in this proceeding is the assignee of the present application, Arteria Medical Science, Inc., The Presidio, P.O. Box 29450, Old Army Headquarters, Building 220, Suite 120, San Francisco, California 94129. Arteria Medical Science, Inc. holds all right, title and interest in and to the present invention and pending application by virtue of an assignment executed on November 5, 2001, November 13, 2001, and November 27, 2001, recorded in the United States Patent and Trademark Office on December 26, 2001, at Reel 012403, beginning at Frame 0795.

(2) Related Appeals And Interferences

None.

(3) Status Of Claims

Claims 1-30 are pending in the application. Claims 6, 10-25, and 30 have been withdrawn from consideration as directed to a non-elected species.

Claims 1, 2, 5, 7-9, 26, 27 and 29 stand rejected as obvious, 35 U.S.C. § 103(a), over Barbut et al., U.S. Patent No. 6,555,057 ("Barbut '057") in view of Barbut, U.S. Patent No. 6,146,370 ("Barbut '370").

Claims 3, 4, and 28 stand rejected as obvious, 35 U.S.C. § 103(a), over Barbut '057 in view of Barbut '370, and

further in view of Zadno-Azizi et al., U.S. Patent No. 6,022,336 ("Zadno-Azizi").

Rejection of claims 1-5, 7-9, and 26-29 is appealed herein.

(4) Status Of The Amendments

No amendments have been filed subsequent to the Final Action.

(5) Summary Of The Invention

The present invention relates to apparatus for controlling cerebral flow characteristics and treating patients suffering from cerebral ischemia caused by thrombus, e.g., stroke. The present application sets forth a system for mechanically removing thrombus from a patient's cerebral arteries, while simultaneously preventing emboli generated during thrombus removal from migrating upstream into the smaller cerebral vessels. The system is intended for use on a patient promptly after onset of the stroke, and before ischemia causes irreversible damage to the brain.

As described in the Background of the Invention portion of the present application, various methods and apparatus are known for attempting to resolve cerebral ischemia by removing the clot. For example, as described at page 1, lines 10-19, systems are known for delivering clot dissolving drugs to treat an occlusion. Such drugs often require several hours to take effect - far longer than brain tissue can survive when starved of oxygen. In addition, such treatments may cause bleeding that results in hemorrhage.

Other previously-known methods and apparatus, such as the Barbut U.S. Patent No. 6,161,547, described at pages 2-3 of the present application, attempt to mechanically aspirate a clot

from a vessel by suctioning the thrombus out of the offending vessel using a catheter located proximal of the clot, while perfusing aspirated blood into a contralateral artery to increase pressure in the opposing hemisphere. Such systems, however, have significant drawbacks, including, potential collapse of the aspirated vessel, and edema of the perfused vessel. Barbut U.S. Patent 6,165,199 and Frazee U.S. Patent No. 5,794,629 include similar drawbacks, as described at pages 3-5 of the present application.

Still other previously known mechanical clot removal methods, such as discussed at pages 5-7 of the specification, attempt to mechanically snare or engage, and then retrieve, the clot. Such systems are expected to damage the intima of the vessel, and more importantly, liberate emboli during the removal process that, in the presence of antegrade flow, may travel still further into the cerebral vasculature and cause additional ischemic events.

In surveying the state-of-the-art of stroke treatment, appellants came to appreciate that to achieve effective stroke treatment, three key features not previously addressed in the art are required: (1) the ability to occlude antegrade flow in the occluded vessel; (2) the ability to aspirate emboli generated during the clot removal procedure; and (3) the ability to control flow through the mid-cerebral arteries to prevent emboli from being carried into collateral circulation. Appellants further discovered that the effectiveness of such a system and methods required a physiologically-mediated aspiration rate to avoid the risks associated with the pump-driven techniques of the prior art.

Appellants' solution to the manifold problems plaguing the prior art stroke treatment systems, as set forth in the present application, provides multiple components for removing

the clot while ensuring that emboli generated during the clot removal procedure do not migrate further downstream into the cerebral vasculature. The principal components of the system are depicted in FIG. 2, reproduced below,

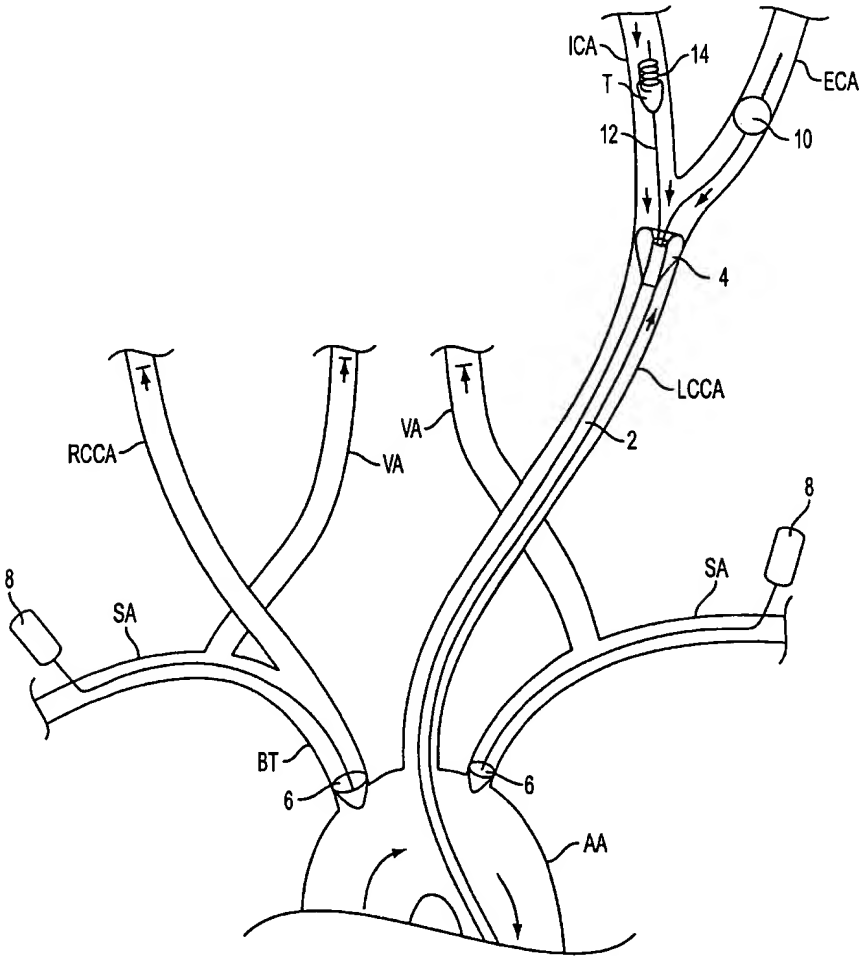


FIG. 2

and include emboli removal catheter 2, thrombectomy wire 12 and one or more flow control devices 8.

Emboli removal catheter 2 is configured to be percutaneously advanced via the descending aorta and includes occlusive element 4. As further described in the specification

at pages 14-15 and 34-35 and depicted in FIG. 3A, emboli removal catheter 2 is coupled at its proximal end to a blood filter and venous return catheter, so that blood and emboli are aspirated through the lumen of catheter 2, filtered, and returned to the patient's circulatory system. In this manner, aspiration of blood from the patient's artery is controlled by naturally-occurring physiologic pressure gradients that exist between the patient's arterial and venous system, thereby avoiding issues of vessel collapse or edema attendant with pump-driven systems.

Thrombectomy wire 12 includes a feature, as shown in FIGS. 6-8, configured to engage and remove a clot from within a vessel.

Flow control devices 8 are deployed, via the radial or brachial arteries, to occlude the flow in the contralateral carotid artery and vertebral arteries, as described at pages 12-14 of the specification. As further therein described, flow control devices 8 permit selective manipulation, i.e., inhibition or redistribution, of flow in the cerebral arteries so that any emboli generated in by thrombectomy wire 12 are directed into the lumen of emboli removal catheter 2.

In accordance with the methods of appellants' invention, emboli removal catheter 2 first is inserted via a femoral access route into the descending aorta, guided through the aorta and aortic arch, and into the left or right common carotid artery (depending on which artery is identified to contain the clot), so that occlusive element 4 preferably is positioned proximal to the carotid bifurcation. The venous return catheter is placed in a remote vein, and coupled to the proximal end of the emboli removal catheter. Next, occlusive element 4 is deployed to occlude antegrade flow in the vessel, and retrograde flow from the internal carotid artery into the lumen of the emboli removal catheter is established by the

physiologic pressure gradient communicated from the venous system to the arterial system via the venous return catheter and emboli removal catheter. To prevent retrograde blood flow from the internal carotid artery from flowing in the antegrade direction in the external carotid artery, balloon 10 may be deployed to occlude the external carotid artery.

One or more flow control devices 8 are inserted separately via the subclavian arteries and brachiocephalic trunk and then deployed to occlude antegrade flow from the aortic arch to the contralateral carotid artery and vertebral arteries. As described in the specification, deployment of the flow control devices causes a redistribution of flow in the cerebral vasculature.

Thrombectomy wire 12 is then advanced to pierce and engage the clot. This step, however, may dislodge emboli distal to the clot ***before*** retrograde flow to the emboli removal catheter becomes established. Accordingly, emboli generated on the distal side of the clot may be carried away by collateral circulation through the mid-cerebral arteries before enough of the clot can be removed to establish retrograde flow into the emboli removal catheter. In accordance with the principles of the present invention, flow control devices 8 permit selective suspension or redistribution of cerebral flow through the mid-cerebral arteries, and thus enhance retrograde flow to the emboli removal catheter while the clot is retrieved.

Independent claims 1 and 26 are directed to the subcombination of emboli removal catheter 2 and flow control device 8. Specifically, the first element of each of claims 1 and 26 is directed to the emboli removal catheter, while the second element of each of claim is directed to a flow control device.

(6) Statement Of The Issues Presented For Review

Do Barbut '057 and Barbut '370, in combination, teach or suggest apparatus for manipulating cerebral blood flow comprising a catheter configured for transluminal retrograde insertion via the descending aorta to occlude antegrade flow in a carotid artery and a flow control device, configured for insertion separately from the catheter, via a subclavian artery and brachiocephalic trunk, to inhibit flow to the vertebral and carotid arteries, thereby controlling mid-cerebral artery flow?

(7) Grouping Of Claims

The issue for determination in this appeal is whether Barbut '057 and Barbut '370 render obvious the invention claimed in independent claims 1 and 26 pursuant to 35 U.S.C. § 103(a), and thus all of claims 1-6, 7-9, and 26-29 stand or fall together.

(8) Argument

A. The Pending Claims Patentably Distinguish Over The Prior Art

(i) The Rejections

The Office action dated September 16, 2003, rejected claims 1, 2, 5, 7-9, 26 and 29 as obvious over Barbut '057 in view of Barbut '370. Claims 3, 4 and 28 were rejected as obvious over that combination further in view of Zadno-Azizi. Appellants respectfully submit that Barbut '057 and Barbut '370 are directed to entirely different fields of endeavor; that one of ordinary skill would have had no motivation to combine any of the disparate elements of those references, nor any expectation that doing so would result in a beneficial result. Accordingly, appellants submit that this appeal may be determined without

needing to consider Zadno-Azizi, which remedies none of the deficiencies of the principal grounds of the rejections.

(ii) The Barbut '057 Patent

Barbut '057 discloses methods and apparatus for isolating and cooling the cerebral vasculature of a patient either in cardiac arrest, during a stopped-heart surgical procedure (such as aortic arch reconstruction), or suffering from shock, head trauma or other cause of diminished circulation. Cerebral ischemia at normothermia will quickly lead to irreversible brain damage. While cooling the brain tissue can extend the vitality of ischemic brain tissue, systemic cooling of the body may result in other complications, such as impaired coagulation. See, col. 2, lines 62 to col. 3, line 10.

The solution proposed in Barbut '057 is to selectively cool the cerebral vasculature. This is done by inserting at least one arterial cannula to perfuse the cerebral vasculature with cooled oxygenated blood from a conventional cardiopulmonary bypass system, and at least one venous cannula to drain the cerebral vasculature. As described in Barbut '057, because during cardiac arrest or open heart surgery there is **no** antegrade flow in the cerebral vasculature, balloon occluders are provided on each of the arterial and venous cannulae to ensure that blood being perfused into, or drained from, the vessels flows to (and from) the brain, rather than being shunted in a retrograde direction to (or drained from) the rest of the body. See, e.g., col. 6, lines 11-13.

The Office Action states at ¶ 4:

> Barbut ('057) discloses, (fig. 6D) a system for cerebral blood manipulation including a catheter 12 having a lumen and an occlusive element at the distal

end ***occluding the antegrade flow in the carotid artery***, and a flow control device (100 or 104) with a flow control element at the distal end configured for insertion separately from the catheter via subclavian artery and brachiocephalic trunk ***so that the flow control device inhibits flow to vertebral and common carotid arteries***" (emphasis added).

The foregoing contention is erroneous, and in fact is ***diametrically opposite*** to the express teaching of the Barbut '057 patent. This is explained with respect to FIG. 6D, reproduced below.

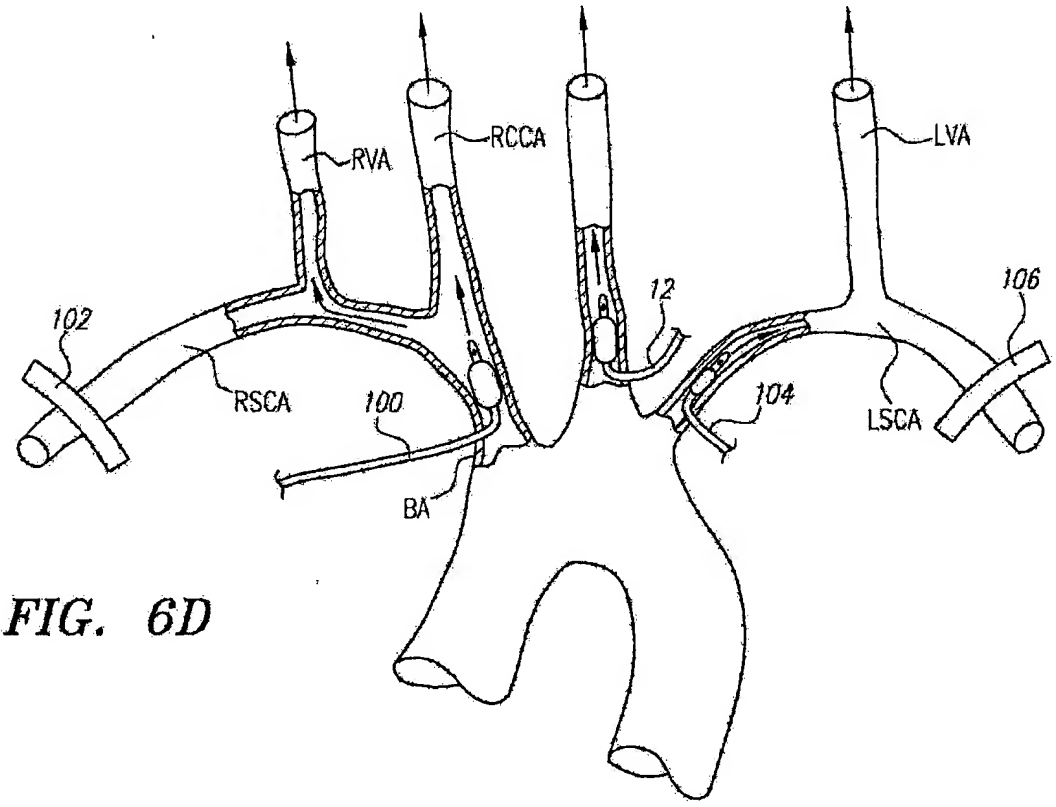


FIG. 6D

As noted above, the goal of the Barbut '057 invention is to selectively ***perfuse*** the brain, ***not inhibit*** blood flow in the cerebral vasculature. The purpose of the balloon occluder on catheter 12 is ***not*** to inhibit antegrade flow - indeed, a patient in cardiac arrest or undergoing

cardiac surgery has no antegrade flow. Rather, as described in Barbut '057, the purpose of the occluder on catheter 12 is to prevent blood from flowing away in a retrograde direction into the aortic arch. See col. 6, lines 18-20 ("At the arterial access site(s), the artery will be occluded to inhibit cold blood ***from flowing into the aorta***.") Accordingly, there is no teaching or suggestion in Barbut '057 that catheter 12 of that invention has "an expanded position wherein the occlusive element ***occludes antegrade flow*** in a carotid artery."

Element 100 of FIG. 6D is identified in Barbut '057 as being "placed into the brachiocephalic artery and ***positioned to perfuse oxygenated medium*** to the cerebral vasculature through both the right common carotid artery and right vertebral artery" (emphasis added). *See*, column 16, lines 43-47 and FIG. 6D. Element 104 is a third-balloon tipped catheter that "is placed in the left subclavian artery relatively near the branch point from the aortic arch ... [so that] oxygenated medium perfused distally of the balloon-tipped cannula 104 ***will flow upwardly through the left vertebral artery*** into the left cerebral arterial vasculature." *See*, column 16, lines 51-68.

When properly read in the context of the invention of Barbut '057, neither of elements 100 and 104 "inhibits flow to vertebral and common carotid arteries" as recited in the pending claims. Instead, the occluders provided on elements 100 and 104 actually ensure antegrade flow through the vertebral and common carotid arteries, rather than inhibit such flow. Like tourniquets 102 and 106, the purpose of the occluders on elements 100 and 104 is to prevent the loss of perfused blood to the rest of the body, not to inhibit flow to the common carotid and vertebral arteries.

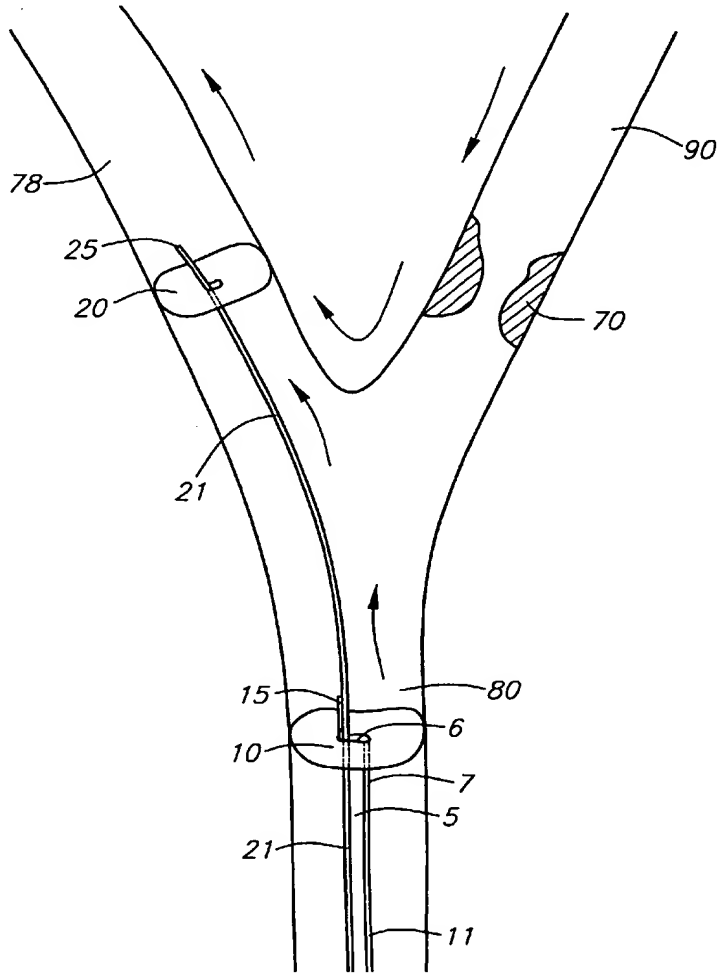
One of ordinary skill reading Barbut '057 would have appreciated that, as the patient is already in circulatory arrest, any effort to inhibit flow to the cerebral vascular would merely hasten the patient's demise. Barbut '057 teaches the desirability of perfusing the cerebral vasculature of patients during cardiac arrest to mitigate the effects of cerebral ischemia. Read in context, and without the hindsight gloss applied in the Office action, Barbut '057 provides no relevant teaching about the desirability of inhibiting flow in the contralateral and vertebral arteries to reduce dispersion of emboli during a thrombus removal procedure. If anything, Barbut '057 teaches the desirability of augmenting (not inhibiting) flow in the cerebral vasculature, which would merely exacerbate the problem that the present invention solves.

Moreover, Barbut '057 fails to disclose an "occlusive element having an opening that communicates with the lumen" as recited in appellants' claims. The claimed emboli removal catheter includes an occlusive element having an opening through which emboli generated during the thrombus removal process are aspirated from the patient. Barbut '057 does not teach or suggest such functionality for catheter 12, and neither does the Office Action address this deficiency. Finally, as even the Office Action concedes, "Barbut ('057) fails to disclose the catheter being inserted via the descending aorta." Office Action, ¶ 4.

(iii) The Barbut '370 Patent

The Office Action looks to Barbut '370 to supply the only feature it contends is missing from Barbut '057, namely, that the catheter be inserted via the descending aorta. As noted above, Barbut '057 is directed to a system for preferentially perfusing the cerebral vasculature to preserve

brain tissue during circulatory arrest. Barbut '370 is directed to devices and methods for preventing embolization of an internal carotid artery during angioplasty of a plaque located in that artery, by redirecting flow to the adjoining external carotid artery. FIG. 6B of Barbut '370 is reproduced below.



The device includes a catheter having balloon occluder 10 and lumen 5 that permits toroidal balloon constrictor 20 to be advanced into the external carotid artery. Although an angioplasty catheter may be advanced through lumen 5 to disrupt lesion 70 in the internal carotid artery, Barbut '370 provides no teaching or suggestion that emboli generated during the procedure should be aspirated via lumen 5. Instead, Barbut '370 discloses that when balloon occluder 10 is deployed, antegrade flow in the common carotid artery ceases and flow reverses in

internal carotid artery and flows into the external carotid artery, as depicted by the arrows in FIG. 6B. Antegrade flow within the external carotid artery is controlled by the degree of constriction imposed by balloon constrictor 20. Accordingly, "embolic debris generated as a result of placing instrumentation within a diseased carotid artery is diverted to the external carotid artery". See, col. 2, lines 27-30.

Although Barbut '370 does suggest a femoral access route for placement of the catheter, col. 6, lines 7-17, nowhere does the patent teach or suggest that any part of the catheter could be usefully combined with a system for selective cerebral perfusion, such as disclosed in Barbut '057, as contended in the Office Action. Moreover, in view of appellants' research, which teaches the importance of avoiding dispersion of emboli even to the external carotid artery, the system disclosed in Barbut '370 would have been disregarded by one of ordinary skill as disclosing a clinically unacceptable solution to the emboli removal problem.

a. The Law of Obviousness

In order to establish a prima facie case of obviousness, three basic criteria must be met:

> "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined), must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure." M.P.E.P. § 2142.

As explained above, the Office Action rejects independent claims 1 and 26, and many of the dependent claims, over the combination of Barbut '057 and Barbut '370. Because a modification to the prior art is required to support this rejection, appropriate motivation to make the proposed modification must be identified to establish a *prima facie* case of obviousness. *See, In re Fritch*, 972 F.2d 1266 (Fed. Cir. 1992).

Barbut '057 provide methods and apparatus for "protecting, perfusing, and optionally cooling the cerebral vasculature of a patient with oxygenated blood or other media" in circulatory arrest. *See*, column 1, lines 16-20. Occlusion balloons are provided to direct the perfused blood in an antegrade direction, not to inhibit such flow. One of ordinary skill would have perceived no value in modifying the system disclosed in the Barbut '057 to inhibit cerebral perfusion, since such a modification would have been contrary to the stated purpose of that invention.

Barbut '370 is directed to devices and methods for redirecting flow from the internal carotid artery to the external carotid artery during treatment of a lesion in the internal carotid artery.

The inventions disclosed in Barbut '057 and Barbut '370 are directed to very different fields of endeavor; comprise distinctly different devices; and are used for completely different purposes. This conclusion is bolstered by the observation that, although both Barbut patents have a common inventor and are commonly assigned, neither patent cites the other, nor do the patents have a single cited prior art reference in common!

As noted above, the goal of Barbut '057 is to perfuse the cerebral vasculature to preserve brain tissue during

circulatory arrest. The goal of Barbut '057 is to ***enhance*** perfusion of the cerebral vasculature -- exactly opposite of the functionality recited for the claimed invention here. Barbut '370, on the other hand, is directed to a device used to induce retrograde flow in the internal carotid artery during angioplasty of a carotid artery lesion. While directed generally to emboli removal, Barbut '370 provides no teaching that inhibiting antegrade flow in the contralateral carotid artery or vertebral arteries would reduce emboli dispersion. For that matter, Barbut '370 actually teaches the (clinically questionable) desirability of dispersing emboli into the external carotid artery. In view of the disparate purposes of the references relied upon, there is ***no*** motivation in the prior art, individually or taken as a whole, to make the combination asserted in the Office action. Nor does the Office action provide any rationale as to why, when read in context, those references would have motivated such a combination.

Even *assuming arguendo* that the references could be combined, which appellants vigorously dispute, the resulting device would not render appellants' claims obvious. Specifically, even if catheter 12 of FIG. 6D were to be inserted via the descending aorta, the resulting system, per the teaching of Barbut '057, would still be a system for preserving brain tissue during circulatory arrest. Because there is no antegrade flow in such a case, the occlusive element of the catheter recited in the first element of the independent claims would not "occlude antegrade flow in a carotid artery." Instead, antegrade flow would be provided by the combined system through the perfusion port of catheter 12. Moreover, catheter 12 of Barbut '057 completely lacks the claimed lumen of the emboli removal catheter used to aspirate emboli from the vessel.

Similarly, elements 100 and 104 of Barbut '057 would continue to perfuse the vertebral and common carotid arteries, not inhibit flow into those vessels, as recited for the claimed flow control device. And as noted above, since the goal of Barbut '057 is to perfuse the cerebral vasculature, the concept of using elements 100 and 104 to inhibit such flow is expressly contrary to teaching of the '057 patent, a deficiency that is not cured by the teachings of the '370 patent. Finally, because the goal of the Barbut '057 system is utterly unrelated to that of the present invention, there would have been no expectation that the combination proposed in the Office action would remotely provide the clinical advantages of the present invention in removing emboli during a thrombus removal procedure.

Accordingly, appellants respectfully submit that neither Barbut '057 nor Barbut '370, alone or in combination, teach or suggest appellant's claimed features of (1) a catheter having an occlusive element having a contracted position that is configured for transluminal retrograde insertion via the descending aorta and (2) a flow control device that is configured for insertion separately from the catheter to inhibit flow to vertebral and common carotid arteries, as recited in claims 1 and 26.

(iv) The Zadno-Azizi Patent

Zadno-Azizi discloses a catheter system for emboli removal during treatment of a lesion by providing a catheter having occlusive devices that form an emboli containment chamber. The containment chamber is used to capture and remove emboli resulting from therapeutic treatment of occlusions within blood vessels. *See*, column 1, lines 13-17. The system is provided with at least two (2) catheters that form irrigation

and aspiration paths. Fluid is provided through the irrigation path to capture emboli present in the blood vessel. Aspiration draws the fluid, and thus, the emboli, into the aspiration path and into the containment chamber. This enables the emboli to be removed from the blood vessel. *See*, column 6, line 54 through column 7, line 44.

Zadno-Azizi, like Barbut '370, is directed to emboli removal, but in a completely different way than in Barbut '370. Zadno-Azizi is a divergent field of endeavor from Barbut '057, and one of ordinary skill in the art would not have looked to Zadno-Azizi to modify Barbut '057. Absent hindsight gleaned from appellant's application, there is no motivation in the prior art to combine any of the features of Barbut '057 and Zadno-Azizi, nor any expectation that the combined device would provide the benefits of appellant's invention.

Appellants accordingly submit that claims 2-6, 7-9, and 27-30, which depend from one of claims 1 and 26, are allowable for at least the same reasons as claims 1 and 26.

Conclusion

In view of the foregoing, appellants submit that the pending claims patentably distinguish over the prior art. Appellants respectfully request that the rejections under 35 U.S.C. § 103(a) be reversed and that the present application be passed to issue.

Respectfully submitted,

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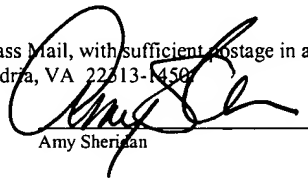
Signature: 

Amy Sheridan

Appendix

1. Apparatus suitable for manipulating cerebral blood flow characteristics, the apparatus comprising:

a catheter having proximal and distal ends, a lumen extending therebetween, and an occlusive element affixed to the distal end, the occlusive element having an opening that communicates with the lumen, the occlusive element having a contracted position configured for transluminal retrograde insertion via the descending aorta and an expanded position wherein the occlusive element occludes antegrade flow in a carotid artery; and

a flow control device having proximal and distal ends and a flow control element disposed at the distal end, the flow control device configured for insertion, separately from the catheter, via a subclavian artery and brachiocephalic trunk so that the flow control device, when deployed, inhibits flow to vertebral and common carotid arteries, thereby controlling mid-cerebral artery flow.

2. The apparatus of claim 1 wherein the occlusive element comprises an inflatable balloon.

3. The apparatus of claim 2 wherein the inflatable balloon further comprises a distal taper.

4. The apparatus of claim 3 wherein the inflatable balloon further comprises a proximal taper.

5. The apparatus of claim 1 wherein the flow control element is inflatable.

7. The apparatus of claim 1 wherein the occlusive element affixed to the catheter is configured to occlude antegrade flow in an artery.

8. The apparatus of claim 1 further comprising:

a shaft having proximal and distal ends; and

a balloon having proximal and distal ends, the balloon being disposed near the distal end of the shaft.

9. The apparatus of claim 8 wherein the balloon is adapted to be disposed in a communicating artery.

26. A system for manipulating cerebral blood flow characteristics, the system comprising:

a catheter having proximal and distal ends, a lumen extending therebetween, and an occlusive element affixed to the distal end, the occlusive element having an opening that communicates with the lumen, a contracted position configured for transluminal retrograde insertion via the descending aorta and an expanded position wherein antegrade flow in a carotid artery is occluded; and

a flow control device, separate from the catheter, having a flow control element configured for insertion via a subclavian artery and brachiocephalic trunk so that the flow control device, when deployed, inhibits flow to vertebral and common carotid arteries, thereby controlling mid-cerebral artery flow.

27. The system of claim 26 wherein the occlusive element comprises an inflatable balloon.

28. The system of claim 27 wherein the inflatable balloon further comprises at least one of a proximal or distal taper.

29. The system of claim 26 wherein the flow control element is inflatable.